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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/472,843	06/07/1995	ROLF J. MEHLHORN	028723-063	1044

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/472,843

Applicant(s)

Mehlhorn

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 17, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-65 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time, filing under 1.29 (a) and the preliminary amendment dated 12-17-01 are acknowledged.

Claims included in the prosecution are 46-65.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 46-54, 56-57, and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Nichols (BBA, 1976).

Nichols discloses disclosed a method of preparation of liposomes using instant method (note entire publication, page 270 in particular). The drugs loaded include epinephrine (page 271). The method involves preparing liposomes with acidic pH and titrating them with a base to create a pH gradient and adding a basic drug such as epinephrine to load the drug.

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3. **Claims 46-54, 57 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Deamer (BBA, 1972) of record.**

Deamer discloses a method of preparation of liposomes using instant method (note entire publication, page 270 in particular). The compounds loaded include are amines (note abstract and Method section). The method involves preparing liposomes with acidic pH and titrating them with a base to create a pH gradient and adding a basic amine.

4. **Claims 46-54, 59 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Cramer (BBRC, 1977) or Kano (BBA, 1978) already of record.**

The references of Cramer and Kano disclose a method of loading substances using pH gradient (note the abstracts). The method involves the preparation of liposomes and lowering the pH of the external medium. The compounds loaded are acidic in nature (note the abstract and Materials and methods).

Claim Rejections - 35 U.S.C. § 103

5. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 46-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols or Deamer or Cramer or Kano cited above.

Nichols and Deamer do not teach the establishment of the pH gradient by the addition of an acid. It is deemed however, to be within the skill of the art of chemistry that if the internal medium is basic one can only establish a gradient by the addition of a acidic substance (that is, altering the pH). Nichols does not teach instant drugs. However, Nichols and Deamer teach the concept of loading a chemical species into the liposomes using a pH gradient. It would have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since Nichols and Deamer teach the principle of loading.

Cramer and Kano do not teach the establishment of the pH gradient by the addition of a base. It is deemed however, to be within the skill of the art of chemistry that if the internal medium is acidic one can only establish a gradient by the addition of a basic substance (that is, altering the pH). Cramer and Kano do not teach instant drugs. However, Cramer and Kano teach the concept of loading a chemical species into the liposomes using a pH gradient. It would have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since both references teach the principle of loading.

Applicant provides no additional arguments to the above rejections in their response. Applicant's previous arguments were addressed by the examiner before.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

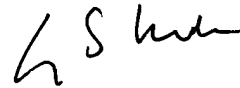
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 1, 2002